

OFFICE OF SPECIAL MASTERS

No. 90-1126V

(Filed: August 4, 2000)

* * * * *

VERONICA FLANAGAN, as parent and *
next friend of ASHLEY FLANAGAN, *

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

* * * * *

TO BE PUBLISHED

Robert Moxley, Cheyenne, WY, for petitioner.
Karen P. Hewitt, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On June 30, 1993, the undersigned issued a decision on entitlement in favor of petitioners in this case. The case concerns Ashley Flanagan (hereinafter, "Ashley") whose seizure onset occurred on-Table after a DPT vaccination with a further seizure flare-up after her MMR vaccination. Ashley has numerous tubers in her brain due to tuberous sclerosis (TS), a condition with which she was born and to which respondent attributes her current condition. The undersigned initially held that Ashley's vaccinations significantly aggravated her TS.

Subsequently, the court took testimony in an Omnibus TS hearing purporting to prove that TS is the known factor unrelated which causes the vaccinees' seizure disorders, mental

retardation, developmental delay, and autism. This hearing resulted in a decision in favor of respondent's factor unrelated defense in those cases in which the vaccinees' seizures occurred in the absence of postvaccinal symptoms like high temperature, anorexia, insomnia, loss of mental affect, and inconsolable screaming and crying. If these symptoms occurred, the undersigned held that further medical proof would be necessary to see if the vaccinee were actually having a neurologic reaction to the vaccine in question. See Barnes v. Secretary, HHS, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997). Unstated, but tacitly understood, was the issue of whether a vaccine injury, once proved, was causally related to the vaccinee's current condition.

On September 24, 1997, the undersigned issued an Order reconfirming the prior decision on entitlement in the instant action in light of the Omnibus TS decision.

On October 7, 1997, respondent moved for reconsideration of the undersigned's decision in favor of petitioner herein based on new evidence. The undersigned granted respondent's motion on December 9, 1997.

In the interim, the parties unsuccessfully attempted to settle this case.

On September 2, 1999, the undersigned heard further expert evidence from the parties in Boston. Respondent's expert was Dr. Gregory L. Holmes, who is not only a pediatric neurologist, but also a specialist in epilepsy and electromyography. Petitioner's expert was Dr. Marcel Kinsbourne, a pediatric neurologist who has previously testified in many vaccine cases.

FACTS

Ashley was born on September 4, 1980. She received her first DPT vaccination on November 14, 1980 at two months of age. She received her second DPT vaccination on January 14, 1981 at four months of age. She received her third DPT vaccination on March 26, 1981 at

six months of age. Med. recs. at 1.¹ Within six hours of her third DPT vaccination, Ashley had convulsions. Med. recs. at 107.

Ashley was admitted to the Stormont-Vail Emergency Room at 8:46 p.m. with a 101.2°F temperature. The admission history notes Ashley having had a DPT vaccination that day, following which she became feverish, vomited, and appeared listless throughout the evening. In addition, Ashley's extremities jerked and she became unresponsive to verbal stimulation. On admission, however, Ashley had eye contact, rolled over, and tried to crawl. She seemed alert and happy. The doctor's impression was that Ashley had suffered a febrile convulsion, ruling out TS. Med. recs. at 107.

Ashley next saw her doctor four days later on March 30, 1981. The results of her neurological examination were completely normal. The doctor noted that Ashley had depigmentation and scheduled a head CT scan for a TS evaluation. Med. recs. at 25.

Ashley's CT scan results, noted on April 3, 1981, showed the presence of tubers. Med. recs. at 26. She had multiple high density areas, the largest on the brain's left side in the periventricular area around the head of the caudate nucleus, a smaller density area on the right side, and other tiny high density areas surrounding the bodies of the lateral ventricles. Med. recs. at 75, 106. Ashley's April 16, 1981 EEG results were normal. Med. recs. at 90.

The May 13, 1981 medical records note that Ashley had a 102°F fever accompanied by vomiting the previous evening. On May 13, 1981, Ashley was afebrile, drinking milk, and behaving well. Med. recs. at 26.

¹ The record in this case is comprised of all filings with the court including petitioner's medical records ("Med. recs."), petitioner's and respondent's exhibits ("P. Ex. __ at __," "R. Ex. __ at __"), and the testimony taken at the hearing ("Tr. at __").

On May 22, 1981, Ashley was taken to Dr. Joseph M. Stein for a neurological consultation. Med. recs. at 75. She had a 103°F fever. She had not seized since March 26, 1981. Later that day, Mrs. Flanagan took Ashley to Stormont-Vail Emergency Room for a pediatric examination. Upon examination, Ashley was awake and alert. While at the hospital, she suffered a seizure. Her head and eyes turned to the right and she made sucking movements with her mouth. All four of her extremities exhibited tremulous movements. She was given Valium to which she promptly responded. The doctor's clinical impression was that Ashley had suffered a febrile seizure, possibly related to her underlying TS. Med. recs. at 99. Consequently, she was placed on Phenobarbital. Med. recs. at 76.

From May 22 to 24, 1981, Ashley was a patient in Stormont-Vail Medical Center. Upon admission, she had a 104°F fever. Med. recs. at 100. By analyzing her urine culture, Dr. G. Van Sickle found that Ashley had pyelonephritis.² As a result, she was placed on Septra suspension in addition to Phenobarbital. Med. recs. at 101.

On June 4, 1981, Ashley was examined. The medical record notes that Ashley's developmental milestones were normal for her age. The physical examination revealed no abnormalities and excellent growth. Med. recs. at 26.

On June 9, 1981, Ashley had a 104°F temperature, loose stools, and a red throat. Med. recs. at 27. On June 10, 1981, Ashley's temperature had dropped to 101°F and she played. Med. recs. at 27. On August 31, 1981, Ashley's Phenobarbital dose was elevated. On September 8, 1981, her mother expressed concern that the elevated dose of Phenobarbital was causing a

² Pyelonephritis is an inflammation of the kidney and its pelvis due to bacterial infection. Dorland's Illustrated Medical Dictionary 1393 (27th ed. 1988).

decrease in Ashley's activity level. Ashley was evaluated as developmentally and neurologically normal. Med. recs. at 27.

On October 3, 1981, Ashley was taken to Stormont-Vail Emergency Room. She had vomited three times at 10:00 a.m., after which she remained asleep. Upon admission, she was limp and lethargic with a 99.4°F temperature. In addition, she was pulling, scratching, and hitting her head with her hands. She was diagnosed with a viral syndrome. Med. recs. at 98.

On October 5, 1981, Ashley visited her doctor. The medical history notes that Ashley had been taken to the Emergency Room on October 3, 1981 for a finger injury. She had been very sleepy without an appetite. She had a 100.2-4°F temperature and was placed on Pedalyte to stop the battering of her head and ears. Upon examination that day, she was alert and active. She was diagnosed with an upper respiratory infection. Med. recs. at 28. On October 4, 1981, Ashley vomited four times.

On December 3, 1981, Ashley saw the doctor for profuse green rhinorrhea and a croupy cough. Her weight gain decreased slightly, but her development was age appropriate. The doctor diagnosed a bacterial upper respiratory infection. Med. recs. at 28.

On January 5, 1982, the doctor administered an MMR vaccination to Ashley. Med. recs. at 29. On January 15, 1982, Ashley had a seizure lasting fifteen minutes. Ashley's seizure was accompanied by a 103°F fever. Following the seizure, she became drowsy. Med. recs. at 97.

From January 15 to 19, 1982, Ashley was a patient in Stormont-Vail Regional Medical Center. On admission, her fever was 100.5°F. She did not have meningeal signs. At 9:52 a.m., she had myoclonic movements in her right arm. At 10:30 a.m., the seizures concluded. The doctor's assessment was that Ashley had suffered status epilepticus. Med. recs. at 97. During her hospitalization, Ashley continuously spiked night time temperatures of up to 104.5°F. She also

had a rash which cleared in two days. Med. recs. at 79. Dr. Van Sickle diagnosed Ashley with TS, a seizure disorder, and resolving viral syndrome. Med. recs. at 96. Ashley was continued on Phenobarbital. Med. recs. at 79.

On January 28, 1982, Ashley visited her doctor. With the exception of rhinorrhea, her examination was normal. In addition, she was developmentally well. Med. recs. at 29.

On March 10, 1982, Ashley visited her doctor again. She had been experiencing balance problems. Her development and growth were age appropriate. Med. recs. at 30.

On April 6, 1982, Ashley returned to the doctor. Her mother indicated that Ashley had had a continuous cold since December. She had rhinorrhea and a frequent, congested cough. The doctor diagnosed bacterial upper respiratory infection and prescribed Amoxicillin. Med. recs. at 30.

Ashley went to the doctor on April 20, 1982 with a temperature of 102.2°F. She had been poking at her ears and feverish for several days. Mrs. Flanagan had a strep throat. Med. recs. at 30.

Ashley visited her doctor subsequently for rhinorrhea and a thigh abscess present since the end of April. On September 9, 1982, Ashley's doctor noted that her development was age appropriate. Med. recs. at 35. In early November, Ashley had a 102.6°F fever but she did not seize. Med. recs. at 81.

The March 11, 1983 office record notes Ashley not having had seizures recently. The doctor could not detect any neurological abnormality. Her language development was appropriate. Her seizure disorder was well controlled, although he thought she might need her Phenobarbital dosage increased. Med. recs. at 35.

In May 1983, Ashley had a 106°F fever and seized for approximately an hour. She then developed a rash on her hands which was thought to be caused by a virus. Med. recs. at 91.

On September 12, 1983, Ashley saw her doctor who wrote that her growth and development were excellent. She had been going to school twice a week. Med. recs. at 37. Ashley saw the doctor on March 7, 1984 and he noted again that she had normal growth and development. Med. recs. at 38.

Dr. Van Sickle recommended Ashley see a neurologist. In a March 27, 1985 letter to Dr. R.E. Baska, he wrote that Ashley had been treated with Phenobarbital since the age of six months. A CT scan performed on April 3, 1981 showed many tubers, predominantly in the periventricular area. Med. recs. at 59.

On April 18, 1985, Dr. Baska wrote to Dr. Van Sickle that Ashley had suffered, by that date, a total of five generalized seizures, all with high fevers. Her last seizure occurred approximately eighteen months before the visit. The majority of Ashley's seizures lasted from 15-20 minutes, but one lasted at least 60 minutes. The seizures were essentially generalized, associated with deviation of the head to the right, and more prominent motor movement in the upper extremities. Ashley had a short attention span, possibly related to the Phenobarbital she had been taking since infancy. She had normal intelligence, cranial nerve, motor, sensory, and cerebellar function. Her EEG results also were normal. Med. recs. at 60-61, 63.

Ashley visited Dr. Van Sickle subsequently for colds, ear infections, and bronchitis. Ashley saw Dr. Van Sickle on June 6, 1986. She was five and three-quarters years old. She could count to 100 and knew colors, her address, and her parents' names. She had been off

Phenobarbital since January without incurring problems. She had a normal growth rate and a normal exam except for adenoma sebaceum³ and huge tonsils. Med. recs. at 42.

The results of Ashley's January 6, 1988 EEG were abnormal, showing intermittent, asymmetrical, left temporal slow wave activity. According to the clinical history, Ashley had had focal jerking on her right side. Med. recs. at 92. A January 19, 1988 doctor's note indicates that Ashley had seizures immediately after she was taken off Phenobarbital. Her throat gurgled and her eyes darted. She lost bladder control and exhibited right arm tonic movements, right facial twitching, and inappropriate speech, all lasting 15-20 seconds. Her school work began to deteriorate around Thanksgiving. Consequently, she was placed on Tegretol. Med. recs. at 45-46.

A February 5, 1988 record indicates that Ashley's teacher said her work was jumbled. Ashley had not had clinical seizures since she was placed on Tegretol, although her doctor wondered whether she had been experiencing subclinical seizures. Her appetite improved. Med. recs. at 46.

On February 22, 1988, the doctor noted that Ashley had three few-second episodes during which she suddenly straightened up, exhibited a blank look, and suffered nausea. Since Ashley's last visit, her teacher had not reported any problems. Med. recs. at 48.

On June 1, 1988, Dr. Van Sickle described Ashley's overall disability as mild. Med. recs. at 68. On July 25, 1988, Ashley had more frequent seizures, consisting of brief muttering, motor activity in her arm, and an episode of loss of bladder control. The doctor switched her to

³ Adenoma sebaceum is the nevoid hyperplasia of sebaceous glands, forming nodules of the face. It involves blood vessels and connective tissue, and is associated with TS. Dorland's, supra, at 28.

Depakote. Med. recs. at 49. An EEG done on July 11, 1988 showed some left frontal spike and wave complexes. Med. recs. at 69, 93.

An August 2, 1988 note states that Ashley had not had any recent seizure activity. Med. recs. at 50. An August 12, 1988 examination revealed that Ashley had had two seizures on two separate days since her last visit, lasting 11 and 15 seconds. She complained of frequent nausea. Med. recs. at 50. A September 13, 1988 note indicates that Ashley had had some breakthrough seizures accompanied by a viral illness. Otherwise, she was doing fine. Med. recs. at 51.

On September 26, 1988, Ashley had an eight-second seizure in the doctor's waiting room. Her right arm jerked. The doctor noted concern with Ashley's possible pubertal development. Med. recs. at 52.

On February 1, 1989, the doctor recorded that between Thanksgiving and Christmas, Ashley had had several seizures with urinary incontinence and her school work had deteriorated. By the date of the examination, her seizures were still occurring, but less frequently, and her school work was improving. Her neurological examination was essentially normal. On June 23, 1989, the doctor noted that Ashley was having four to five seizures over a four-day period monthly. Med. recs. at 53, 54, 71.

On November 11, 1989, Ashley's doctor sought another doctor's advice. Ashley had been continuously seizing. The doctor wondered if Ashley's predictable monthly seizures were related to hormonal fluctuations even absent frank puberty. He called this catamenial epilepsy.⁴ Mrs. Flanagan thought Ashley's seizures were no longer predictable. Med. recs. at 55.

⁴ Catamenial pertains to menstruation. Dorland's, supra, at 282.

On April 24, 1990, the doctor noted that Ashley had seized on January 22-24, February 13-15, March 17-19, and April 15-17. Ashley's seizures had changed somewhat. During episodes, she exhibited shrill cries and arm movements lasting 30 seconds. Following seizures, Ashley suffered headaches but did not become sleepy. Med. recs. at 55. On May 8, 1990, the doctor recorded that Ashley had had two seizures on May 4, 1990, but otherwise had been doing okay. Med. recs. at 56.

On May 24, 1990, Ashley was placed on Amoxicillin. On May 30, 1990, Ashley's seizures increased greatly. When her Amoxicillin was decreased, she stopped having seizures. The doctor queried whether or not Ashley's seizures were related to intercurrent infection or Amoxicillin. Med. recs. at 57.

On July 24, 1990, the doctor noted that Ashley had had seizures on June 5 and 6. She was then placed on Diamox and the seizures stopped. Once the Diamox was decreased, she had seizures three days in a row. Her seizures consisted of guttural noises and a jerking right arm but no loss of consciousness. Med. recs. at 58.

Dr. Baska evaluated Ashley on March 6, 1991. Thereafter, he wrote a letter to Dr. Van Sickle concerning her condition. Ashley had been having at least one seizure weekly and as many as four to eight seizures daily. Her seizures lasted a few seconds and consisted of right arm flexion and guttural or throaty noises. During episodes, Ashley lifted her left hand to her throat. Her school performance and behavior had deteriorated. Other children at school had been teasing her. Dr. Baska recommended increasing Ashley's dose of Diamox. Thereafter, her seizures continued to occur primarily toward the end of her menstrual month.

On June 15, 1991, Ashley saw Dr. Peter Huttenlocher, a pediatric neurologist and expert in TS, at the University of Chicago. In his report, he wrote:

Ashley has had fairly normal developmental progress. She walked at 11½ months, began to talk at the same time, and had sentences during the second year of life. She was toilet-trained at age 2 years. Presently she attends fifth grade, where she is partly mainstreamed, but also receives LD help in reading, math, and speech. Recently the child has become somewhat insecure and withdrawn, perhaps related to peer pressures.

P. Supp. med. recs. at 1-2.

Dr. Huttenlocher wrote that according to the medical history, Ashley's seizures, beginning at six months of age, were treated initially with Phenobarbital, which made her lethargic. At six years of age, Ashley was placed on Carbamazepine, but it led to weight gain. Since Ashley was seven years old, she had been on Depakote, to which Diamox was added in 1989. On weekends, Ashley did not take medication and suffered seizures.

Ashley's initial EEG in 1981 at six months of age was normal. Ashley's 1988 EEGs showed left frontal and left temporal spike activity. A CT scan at 7 months of age showed typical periventricular calcifications, including a large one near the left foramen of Monro. MRIs done in July and November 1990 showed multiple periventricular lesions and a large number of cortical tubers in the left temporal and right and left frontal regions.

On examination, Dr. Huttenlocher found that Ashley did not have weakness, change in muscle tone, or reflex asymmetry. He recommended that Ashley attend summer school, consider psychological counseling, and begin a trial of Depakote and Tegretol. If that combination failed to improve her seizure control, he suggested epilepsy surgery because Ashley's seizures had been stereotyped and focal since early infancy and her large tuber in the left temporal area might well be triggering her attacks.

WRITTEN TESTIMONY

Dr. Manuel Gomez wrote a letter to respondent. R. Ex. R. Next to the last page, he states that Mrs. Flanagan described many varieties of Ashley's seizures. "This great variety of epileptic seizures point [sic] to a multiple origin in the ... cerebral cortex of the seizure discharges. This is what one may expect from multiple cerebral epileptogenic foci as it is often the case in individuals with TSC [tuberous sclerosis complex] who harbor multiple cortical tubers."

TESTIMONY

Dr. Gregory L. Holmes testified first for respondent.⁵ Tr. at 4. He is the director of pediatric research in epilepsy and a staff neurologist at Children's Hospital and teaches basic neuroscience and neurology on the faculty at Harvard Medical School. Tr. at 6. He has studied the effects of seizures on the epileptic brain in rats and works on animal models of brain dysgenesis or cerebral malformations to study seizures. Tr. at 10. The outcome in the rat depends on its age as well as the number and duration of seizures. *Id.* There are two major groups of rat seizures:

1. Partial seizures with secondary generalization, and
2. Generalized seizures from myoclonic jerks to tonic-clonic seizures. Tr. at 11.

Dr. Holmes is the primary author of 100 papers, and the secondary or contributing author of 60 papers. Tr. at 14. He has published on febrile seizures. *Id.* He is on the boards of the *Annals of Neurology*, *Clinical Neurophysiology*, and *Epilepsy Research*. Tr. at 15. He sees 50 to 100 patients a month. *Id.* Of his patients, 95 to 98 percent have seizures. Tr. at 16. His main

⁵ The undersigned had respondent put her witness on first because she bore the burden of proving a factor unrelated caused Ashley's current condition.

interest is epilepsy. *Id.* He has 15 TS patients currently, and has had about 70 TS patients over twenty years. *Id.* He has spoken at the national meeting of the TS association. *Id.*

Dr. Holmes' opinion in this case is that TS is the cause of Ashley's current condition. Tr. at 18. TS is a genetic disorder with central nervous system pathology, hamartomas, periventricular lesions, and subependymal lesions. *Id.* TS is highly associated with seizures, mental retardation, and autism. *Id.* Dr. Holmes reviewed Ashley's MRI. *Id.* She has 23 tubers located in the frontal, parietal, and temporal lobes bilaterally. Tr. at 19. She has very extensive and severe TS. *Id.* Dr. Holmes would expect Ashley to have difficult to control seizures, developmental delay, or mental retardation. Tr. at 19.

Her cortical tubers are an abnormal configuration of cells, putting her at high risk for having seizures and epilepsy (epilepsy means two or more unprovoked seizures). Tr. at 20. Status epilepticus is a single seizure that lasts at least 30 minutes. Tr. at 21.

TS is a disorder of migration and configuration. Tr. at 22. Neurons are born in the inner part of the brain and migrate outward. *Id.* With TS, many of the neurons and glia cells (the supporting network for the brain) are abnormally configured. *Id.* Scientists have identified the genes that cause TS. Tr. at 23.

Ashley did not have any problem with her first and second DPT vaccinations. *Id.* She had one fever the week before her third DPT, but did not seizure. *Id.* In explaining why she did not seize with this fever, Dr. Holmes said that many children who have seizures with fever do not seize with every fever. *Id.* The reason may depend on factors such as the duration of the fever, the nature of the cause of the fever, the hydration status of the individual, and whether the individual slept the night before. Tr. at 24.

On March 16, 1981, Ashley had been put on antibiotics. *Id.* On March 26, 1981, when she received the third DPT, she was still on antibiotics. *Id.* After her vaccination, Ashley had a seizure involving the left side of her brain, lasting two minutes. Tr at 25. At the emergency room, she made eye contact, moved about, and looked fine. Tr. at 25-26. Her neurological examination was reported as within normal limits. Tr. at 26. She was not put on anticonvulsants. *Id.* The diagnosis was febrile seizure because the doctors thought it was benign. *Id.* Ashley's seizure has a right focal component. *Id.* She did not have symptoms of acute encephalopathy. Tr. at 26-27.

DPT can lead to fever and fever can lead to seizures. Tr at 29. Fever caused Ashley's seizure. Tr. at 27-28. TS created a low seizure threshold in Ashley. *Id.* Also, she has a family history of febrile seizures. *Id.* Ten members of her family had febrile seizures. Tr. at 28. Dr. Holmes opined that Ashley's March 26, 1981 DPT could have caused her fever. Tr. at 29. If DPT did cause the fever, causing her to seize, this still had no permanent effect on Ashley because a brief (two-minute) seizure does not alter the seizure threshold. Tr. at 29-30. Medical literature does not support the view that once a TS child seizes, he or she is on a downhill course after that. Tr at 31-32. Dr. Holmes' own experience does not support that idea either. *Id.*

Seizures that occur in TS children in their first year of life are difficult to control. Tr. at 32. The bad outcome from early onset of seizures in TS occurs only with infantile spasms, which are bad for the brain. Tr. at 33. According to Dr. Holmes, other seizures, like complex partial seizures, can also cause damage to the brain, but it is the underlying disease, not the seizures themselves, causing the damage. Tr at 35-37. Ashley had complex partial seizures from

the beginning.⁶ Tr. at 36. Ashley later developed a seizure disorder as a result of her TS, not as a result of her initial febrile seizure. Tr. at 40-41. There is no indication that a two-minute seizure is capable of producing epilepsy. Tr. at 40.

Ashley's first seizure was a benign febrile seizure. Tr. at 43-44. She was fine in the ER, and had a normal neurological examination without any medication prescribed. Tr. at 44.

Ashley's seizure disorder onset was at five years of age when she was taken off Phenobarbital and had afebrile seizures. Tr. at 45. A seizure disorder is epilepsy only if the seizures are afebrile. Tr. at 46. Ashley had five seizures in her first five years of life all associated with fever. Tr. at 47-48. This was not epilepsy. Tr. at 48. The trigger was fever. *Id.*

On May 22, 1981, Dr. Stein, a neurologist, saw Ashley. Tr. at 48. (Dr. Holmes mistakenly said May 25, 1982). She had a fever of 104 degrees in his office and went to the ER where she had a seizure. Tr. at 49. She was started on Phenobarbital. *Id.* On January 5, 1982, Ashley received MMR vaccine. *Id.* Ten days later, on January 15, 1982, she had a febrile seizure for 15 minutes. *Id.* This was not status epilepticus. Tr. at 66. Her white blood count showed elevated atypical lymphocytes which indicated she had a viral illness. Tr. at 50. Her rhinorrhea (runny nose) suggested a viral infection. Tr. at 51. Dr. Holmes testified that rashes are common in children and are seen with viral infections. *Id.* Ashley had a normal EEG with no indication of epilepsy. *Id.* The doctor took her off Phenobarbital and she was seizure-free for two years. Tr. at 52. Subsequently, Ashley had afebrile seizures, went back on medication, and started a terrible cycle. Tr. at 54-55. No one knows if the afebrile seizures caused Ashley's problems. Tr. at 56.

⁶ A complex partial seizure is one in which there is impairment of consciousness. Tr. at 40.

Dr. Holmes testified that TS caused Ashley's seizures. *Id.* He said that a two-minute seizure in the context of fever does not do any damage. Tr. at 58. Afebrile seizures of up to an hour's duration occurring 10 to 30 times per month are damaging. Tr. at 59.

Ashley's five seizures in her first five years were not damaging or dramatic. Tr. at 59-60. Her IQ was normal when she was 8 years old in 1988 (91 IQ). Tr. at 61. When she was 10 years old in 1990, her IQ was low average (84 IQ). *Id.* When she was 16 years old in 1996, her IQ was 60 to 65. *Id.* This is not an uncommon scenario in TS and non-TS children. Tr. at 62-63. Ashley did not acquire new skills. Tr. at 63. Frequent seizures accumulate over time and do cause damage. *Id.*

Ashley's seizure after MMR did not cause her later seizures and was not status epilepticus because it was too short (not 30 minutes). Tr. at 66. The medical literature is clear that the vast majority of children with febrile seizures develop afebrile seizures. Tr. at 67. Dr. Holmes referred to respondent's exhibit MMM, the Hirtz article, regarding seizures after DPT or MMR. Tr. at 68-70. All but one of the seizures in the article were associated with fever and closely resembled febrile seizures. Tr. at 69. None of the children developed epilepsy. *Id.* Many had a family history of seizures as well. *Id.* The children were normal at seven years of age. *Id.* None of the children in the article had TS. Tr. at 70.

Dr. Holmes discussed respondent's exhibit NNN, the Jozwiak paper, to show that DPT is unrelated to poor mental development in TS patients. Tr. at 72.

Ashley had a lower seizure threshold due to her TS. *Id.* Her post-DPT seizure did not cause her current condition. Tr. at 72-73. Dr. Holmes does not know if she would have been normal if she had not had seizures. Tr. at 73. Having 23 tubers put her at risk for seizures. *Id.*

The number of tubers determines the severity of the disease. *Id.* The location of tubers may be important as well. Tr. at 74.

Ashley has had only right focal seizures. *Id.* They are coming from her left hemisphere. *Id.* A question is whether she is an appropriate candidate for surgery. Tr. at 75. There is a big motor component to Ashley's seizures. Tr. at 75.

Dr. Holmes was asked if TS children need an external event such as fever to start them seizing. Tr. at 77. He answered that they can, but they can also seize without fever as in infantile spasms. *Id.* In Ashley, the external event was the fever. Tr. at 78. Stress also triggers Ashley's seizures, according to Dr. Van Sickle. *Id.* DPT could have been the stress, but more likely, the stress was the fever. *Id.* There was no immediate developmental regression in Ashley. Tr. at 80.

Jozwiak's sample was a clinical, not a population-based, study, and is inherently biased. Tr. at 84. There is no large population study of DPT and TS. Tr. at 81. Dr. Holmes did not agree that there is no convincing literature other than the Jozwiak article that TS children are not at greater risk for immunization-related neurological injury. Tr. at 84-85.

Petitioner's counsel referred Dr. Holmes to respondent's exhibit MMM, the Hirtz, Nelson, and Ellenberg article, which posits that seizures are related to immunization if their onset is within two weeks in contrast with the Jozwiak study which does not set a reasonable period of time between DPT inoculation and the first seizure. Tr. at 87-90. Dr. Kinsbourne, for petitioners, interjected that Jozwiak should have compared the TS-DPT (experimental group) with the TS-non-DPT. Tr. at 91-92. Dr. Holmes said that Jozwiak tells us whether the history of DPT affects mental outcome, not whether DPT triggers seizures. Tr. at 98.

Respondent's exhibit PPP is an editorial about animal studies which induce neuronal migration disorder in rats. Tr. at 100. Dr. Holmes could make some inferences from this study of mesial temporal sclerosis (MTS) for TS patients. Tr. at 100-101. The rats had lower thresholds to febrile seizures. Tr. at 102. Fever caused cell death in the rats. *Id.* Petitioner's counsel queried whether TS children were more susceptible to neuronal damage. *Id.* Dr. Holmes replied they were not. *Id.*

Dr. Holmes referred to respondent's exhibit VVV, the Germano paper, which shows cell loss independent of seizure activity. Tr. at 103.

One week before she received her third DPT, Ashley had 103 degree fever, but did not suffer any damage. Tr. at 104. Respondent's exhibit LLL distinguishes between benign and non-benign febrile seizures. *Id.* Focal seizures can be benign even though complex. Tr. at 105. They may involve more risk for developing epilepsy, but not necessarily intractable epilepsy. *Id.* Dr. Manuel Gomez, in his letter to respondent's counsel (R. Ex. R), states that Mrs. Flanagan's testimony indicates that Ashley may have had more than five seizures in her first five years. Tr. at 105-06. She described a lot of blank stares, nausea, and sleeping a lot. Tr. at 108. However, she did not describe complex partial seizures. Tr. at 109. Dr. Holmes doubted that Ashley was having seizures other than her five. *Id.* Most blank stares are not seizures nor is hitting her head or turning red. *Id.* If a focal seizure lasts thirty minutes or there is more than one in 24 hours, the risk of developing into epilepsy increases only 15 percent. Tr. at 112. Ashley's treating doctors did not diagnose her blank stares as seizures. *Id.* If the stares had been seizures, Dr. Holmes said his opinion would remain the same that Ashley would have developed afebrile seizures. Tr. at 113. She would not have been doing well neurologically and have had a normal EEG if she had been having constant seizures during her first five years of life. Tr. at 113-14.

Dr. Holmes admitted that some of the medical literature to which he referred omitted TS patients from their studies. Tr. at 115. Other studies included TS. *Id.* Respondent's exhibit WWW, "Intractable Epilepsy" by Fois, is not specifically on TS. Tr. at 115-16. All children with TS had uncontrolled epilepsy. Tr. at 116. The risk of having uncontrolled epilepsy did not increase with febrile seizures. *Id.*

Dr. Marcel Kinsbourne testified on behalf of petitioner. Tr. at 117. His opinion is that Ashley had antecedent TS, and DPT significantly contributed to her outcome. Tr. at 118. He did not have an opinion on the role of the MMR vaccine in Ashley's outcome. Tr. at 118-19. The basis for his opinion on the effect of DPT is that children with TS differ radically from normal children because the latter's seizure threshold is normal. Tr. at 120. The risk factor for clinical seizures in TS children is to lower the seizure threshold. *Id.* Fever, sleep deprivation, intercurrent illness, and DPT can further lower the seizure threshold, and a seizure results. *Id.* Once a TS patient has a seizure, the chance of more seizures is extremely high. *Id.* Once the seizure threshold is lowered in a TS child, it stays low and further seizures can be unprovoked. Tr. at 121.

In Ashley, a particular tuber suffered a lower seizure threshold. *Id.* The form of Ashley's seizure disorder has been remarkable. *Id.* It is right focal, and resulted in vomiting, sleepiness, and lethargy. *Id.* Dr. Kinsbourne believes that she had unobserved seizures in her first five years. Tr. at 121-122. Only one of Ashley's tubers keeps discharging. Tr. at 122.

Dr. Gomez recommended surgical removal of her epileptic tuber. Tr. at 122. Dr. Katz at Menninger recommended resection. Tr. at 122-23. Dr. Huttenlocher also recommended excision of her left temporal area. *Id.* Ashley did not show the mental retardation that one sees after infantile spasms. Tr. at 123. She has pervasive developmental disorder (PDD). *Id.* It is like

autism and is characterized by behavioral changes, but not the lowering of the IQ. *Id.* Dr. Thompson, in the Mercy Hospital, Kansas City report (P. Ex. 18, p. 2), states that, as an infant, Ashley was not interested in engaging with people, which Dr. Kinsbourne calls autistoid. Tr. at 124. By age three, she was spinning around in circles, which he also called autistoid. *Id.* The origins of her damage were thus perceptible well before the Phenobarbital was stopped and the afebrile seizures began. Tr. at 125. Ashley has a “temporal lobe personality.” *Id.*

Petitioner’s Ex. 18, p. 29, describes Ashley as having overwhelming behavioral problems including vicosity (diffuse insistence) and hypergraphia (writing too much). Tr. at 125-26. Left temporal lobe tubers cause autistic problems in TS children. Tr. at 127. Dr. Kinsbourne opined that Ashley had a single, continual flow of events. *Id.* He would not distinguish between her first seizure and the ones that followed. Tr. at 128.

Each tuber has its own seizure threshold. *Id.* A very familiar finding in seizure disorders is that fever very frequently provokes seizure disorders when the child is young, but plays less of a role later. Tr. at 129. Dr. Kinsbourne does not know if seizures caused the atrophy seen on MRI. Tr. at 131. Once the seizures take hold, however, there are problems with central development and personality. *Id.* Continued seizures maintain the lower seizure threshold. *Id.* The location of the focal tuber is important. Tr. at 132.

Dr. Kinsbourne testified that he is not committed to one cause of Ashley’s condition. *Id.* Her current condition suggests something is wrong with the left temporal lobe. Tr. at 133. He thinks this is a functional disturbance due to subclinical seizures. *Id.* Temporal lobe seizures come from deep in the brain and do not always appear on EEGs. Tr. at 134. Seizures are gross behavioral changes. Tr. at 135. Subclinical seizures are occasionally flares. *Id.* Dr. Kinsbourne stated he would not separate TS from DPT as the cause of Ashley’s current condition. Tr. at

135-36. TS is a massive risk factor. Tr. at 136. DPT is a convergent, i.e., a necessary stress-factor in her dysfunction. *Id.* He does not know when Ashley would have had seizures without DPT. Tr. at 138.

Dr. Kinsbourne testified that early seizures are more likely to lead to intractable seizures. *Id.* He thinks that epilepsy has no clinical significance. Tr. at 139. Ashley's first seizure was not a benign febrile seizure. Tr. at 140. It was complex and focal. Tr. at 140-41. Ashley's fever showed that she had a systemic reaction to DPT. Tr. at 142-43. Ashley's condition is a sequela of her TS and DPT. Tr. at 144-45. He does not know if DPT vaccine got into Ashley's brain. Tr. at 145. There are three possibilities: (1) DPT got into her brain, or (2) DPT generated a fever which lowered the seizure threshold, or (3) both 1 and 2. *Id.* DPT contains toxins (pyrogens) which get into the brain. *Id.* When asked why Ashley did not have a seizure the week before the third DPT when she had a fever of 103 degrees, Dr. Kinsbourne stated that DPT contains something which, when combined with fever, causes a seizure. Tr. at 146.

Dr. Kinsbourne admitted that fever and a seizure were Ashley's only two symptoms after her third DPT. Tr. at 147. Mrs. Flanagan testified at the prior hearing that Ashley had blank stares and nausea during her first five years, but did not mention a right focal component or jerking. Tr. at 148. Ashley has frank right motor focal seizures occasionally with vomiting before and lethargy afterwards. Tr. at 149. Mrs. Flanagan also reported staring spells. Tr. at 150. Ashley has more than right focal seizures. Tr. at 150-51.

Dr. Holmes stated that Ashley did not have absence seizures. Tr. at 151. They were a generalized seizure type. *Id.* Mrs. Flanagan's description during her testimony did not convince him. *Id.* It would be rare to have blank stares that were seizures without other symptoms. *Id.*

Dr. Kinsbourne stated that Ashley did not have absence seizures but brief interruptions of consciousness. Tr at 164.

Ashley has had additional fevers without seizures, which is to be expected. Tr. at 152-53. She had two prior DPT vaccinations with no adverse reaction. Tr. at 153. The stage of maturation is very important in seizure onset. *Id.* She has ten relatives with febrile seizures, putting her at high risk for benign febrile seizures. Tr. at 153-54.

Dr. Kinsbourne was asked if his theory that DPT toxin injures the brain is a minority view. Tr. at 154. He said no: the majority thinks that DPT damages the brain and the Institute of Medicine and the National Childhood Encephalopathy Study state that a toxin as the mechanism of damage is plausible. *Id.* But his view of how toxins get in the brain and harm (i.e., as endotoxins) is a minority view. *Id.* Drs. Menkes and Aicardi agree with him; Drs. Fenichel and Golden do not. Tr. at 156. Dr. Kinsbourne has not cited any medical literature in his reports. Tr. at 157.

On rebuttal, Dr. Holmes testified that, on March 26, 1981, Ashley's first seizure did not have any sequelae. Tr. at 165. It was very brief and she looked fine. Tr. at 165-166. No DPT toxins invaded her brain. Tr. at 166. Her autistic symptoms did not follow her febrile seizures. Tr. at 168. A 1995 record refers to Ashley having autistoid behavior, but there is no contemporaneous record of it. Tr. at 169. Dr. Holmes disagrees that a single seizure resets the child's seizure threshold. *Id.* "Kindling" occurs in monkeys where they have 100 seizures and a lower seizure threshold, but this has not been shown in humans. Tr. at 170. Dr. Kinsbourne stated that Ashley's first seizure made a difference to her seizure threshold. Tr. at 172.

DISCUSSION

At the very outset, the court can see agreement between the two experts. They both agree that DPT produced a fever in Ashley which resulted in her onset of seizures. They disagree on the consequence of the onset of that first seizure. Dr. Kinsbourne posits a theory that DPT or the fever or both resulted in the lowering of the seizure threshold of one and only one of Ashley's 23 tubers. Dr. Holmes presents the view that seizures are a typical symptom of severe TS, which Ashley has, and that the brevity and infrequency of her five seizures during the first five years of her life, plus her maintaining her milestones and intelligence for years, indicate that TS is the cause of her current condition, not her initial seizures, which were all febrile. Dr. Kinsbourne, on the other hand, thinks that both TS and Ashley's seizure disorder harmed her, that she had unobserved seizures in the first five years of her life, and that she had autistoid traits of not engaging with people and spinning in circles during that time. MMR is not at issue because Dr. Kinsbourne did not have an opinion on its role in Ashley's outcome.

The literature does not support Dr. Kinsbourne's view that the brief seizures, post-vaccination, which were not infantile spasms, were in themselves harmful to Ashley's brain. Only infantile spasms, status epilepticus, and repetitive afebrile seizures have been shown to be harmful to the brain. Eventually, when Ashley was taken off Phenobarbital for the second time when she was five years old, she suffered documented afebrile seizures and began her developmental decline.

Dr. Kinsbourne believes that Ashley's blank stares, which are not in the medical records but about which Mrs. Flanagan testified, were actually seizures, while Dr. Holmes said they were not. In this battle of the experts, the court must lean toward Dr. Holmes who actually has a clinical pediatric neurologic practice and current and past TS patients, and teaches at Harvard Medical School, whereas Dr. Kinsbourne has not been in practice for ten years and teaches non-

medical students about the organic basis for psychological problems at the New School for Social Research, a non-medical school.

Accepting Dr. Holmes' testimony over Dr. Kinsbourne's that Ashley's blank stares, if they occurred, were not seizures, the court has no basis to conclude that Ashley's autistoid tendencies and ultimate developmental delay are related to anything but her TS. First, as Dr. Kinsbourne testified, her autistoid tendencies began at two years of age, which is one and one-half years after the onset of her seizures. Second, her decline in intelligence and other skills did not occur until she was ten years old, which was nine and one-half years after the onset of her seizures.

In Lampe v. Secretary, HHS, No. 99-5050, ___ F.3d___ (Fed. Cir. July 31, 2000), the Federal Circuit affirmed the dismissal of a causation in fact and, in the alternative, significant aggravation case inter alia because of the great passage of time elapsing between vaccination and developmental delay:

The passage of time between an event and the consequences that are alleged to flow from it is often significant, and . . . it was not improper for the special master to attach some significance to the lengthy period of delay between the vaccination and the deterioration in [the vaccinee's] condition.

Id. slip op. at 21.

In Lampe, the "lengthy period of delay" was two years and eight months (the vaccinee received her DPT at four months of age and her developmental delays occurred between ages three and six years). In the instant action, the lengthy period of delay is over three times that in Lampe. For this reason alone, Dr. Holmes' testimony that there is no causal relationship between

Ashley's initial seizures and her ultimate developmental delay is more credible than Dr. Kinsbourne's.⁷

Ashley may have had damage from her seizures once they became afebrile at age five, but that is the normal course of a TS-caused seizure disorder unfortunately. Dr. Kinsbourne posits that had she not seized at all, she would not have developed afebrile seizures years later and, therefore, never have suffered from developmental delay. But in a TS child with 23 tubers, that is not a credible argument. The court believes Dr. Holmes that, at some point, Ashley would have seized. Children with severe TS generally go on to seize, as well as to develop autism, developmental delay, and mental retardation.

This is not a case in which a TS child manifests infantile spasms and then experiences a decline in mental ability within weeks or months. Ashley manifested sporadic febrile seizures which were unaccompanied by an acute encephalopathy. Dr. Kinsbourne's theory of DPT invading the brain seems inappropriate to the medical facts of this case because, other than a fever after the third DPT, she did not have any systemic reaction to the vaccination. No one addressed her vomiting and listlessness the evening of the vaccination.

The Vaccine Act gives petitioner the presumption that the third DPT caused Ashley's onset of seizures, but not that her current condition is due to that onset so that she prevails on a theory of significant aggravation. Contra Gruber v. Secretary, HHS, No. 95-34V, 1998 WL

⁷ If Ashley had autistoid tendencies at the age of two years (which is not substantiated in any contemporaneous record), there is still an interval of one and one-half years between seizure and autistoid tendency. This is a sufficient interval to belie causation. Moreover, the undersigned has not heard any credible testimony that brief seizures cause autistoid tendencies. On the other hand, the undersigned has heard credible testimony, in this and other TS cases, that TS leads to autism. The earliest record to note this autistoid behavior, according to Dr. Holmes, is in 1995, hardly contemporaneous with occurrences purportedly taking place over a decade before.

928423 (Fed. Cl. Spec. Mstr. Dec. 22, 1998). This case, like McMurry v. Secretary, HHS, No. 95-682, 1997 WL 402407 (Fed. Cl. June 27, 1997), deals with DPT causing a fever which triggers a seizure. But unlike McMurry, in which respondent could not prove a known factor unrelated led to the vaccinee's current condition, here Ashley has TS which, particularly in its severe form, is known to lead to developmental delay, afebrile seizures, and autism.

Seizures are not necessarily harmful in all cases. Here, where there are initially very brief seizures that are not followed for years by developmental delay, it begs credulity to link causally the appearance of the seizures in Ashley's first five years with her later developmental delay and mental retardation.

Autism is another symptom of severe TS. No one, certainly not in this case, has related autism or autistoid behavior to seizures or even to blank stares if they were seizures. If Ashley's first five seizures did not worsen her preexisting TS, then their onset is unrelated to the onset of her autistoid behavior, assuming the 1995 record is correct. There is no credible evidence that Ashley's initial seizures had anything to do with her later autistoid behavior.

Similarly, Ashley's mental retardation and developmental delay are an expected outcome of her severe TS. It could be, as Dr. Holmes testified, that the accretion of afebrile and uncontrolled seizures after Ashley was five years old and taken off Phenobarbital led to her developmental delay and mental retardation or they could be a direct result of her TS, or a combination of the two.

This case resembles Jordan v. Secretary, HHS, No. 91-0113V, 1998 WL 106131 (Fed. Cl. Spec. Mstr. Feb. 23, 1998). Kara Jordan was born with an autosomal recessive genetic disease resulting in her having neonatal seizures and absent organs. She was put on anticonvulsants and her seizures stopped. After her second DPT vaccination, her seizures resumed and worsened.

She lost all her milestones. However, when she was put on anticonvulsants again, her seizures were controlled and she regained her milestones. Seven months later, while her mother was watching her, Kara stopped breathing and died. She did not have a seizure. Breathing difficulties had plagued her from birth. This court held that she suffered a vaccine injury but that there was no causal relationship between the vaccine injury and her death, and dismissed the case.

In the instant action, respondent's proof does not rebut the statutory presumption that DPT triggered Ashley's first seizure by causing a fever that caused the seizure. However, petitioner's burden of proof is not satisfied because, although Ashley's current condition is significantly worse than her pre-vaccination condition, petitioner must prove a causal relationship between the vaccine injury and the current condition, i.e., that the current condition is the sequela of the vaccine injury, in order to prevail. Song v. Secretary, HHS, No. 92-279V, 31 Fed. Cl. 61 (Mar. 29, 1994); Hossack v. Secretary, HHS, No 91-1528V, 32 Fed. Cl. 769 (Feb. 3, 1998). See also Lampe, supra, in which the Federal Circuit, in denying there was significant aggravation of previous seizures, focused on the lengthy period of delay between seizure and developmental delay to note no causality. Contra, Gruber, supra.

There is no causal nexus between Ashley's vaccine injury (the first seizure) and her current condition (autistoid behavior, mental retardation, and developmental delay). Based on Dr. Holmes' testimony, the court cannot see how her initial seizures consisting of five febrile seizures over four and one-half years led to any of her damage. She did not have infantile spasms. Her initial seizures were sporadic and not accompanied by acute encephalopathy. Her autistoid behavior, if it occurred early on, was a parallel development, quite in keeping with the expected course of someone with severe TS. It is probable that Ashley would have had seizures

anyway because of the severity of her TS. Dr. Holmes testified that Ashley's seizures after she was five years old, which were afebrile, were caused by her TS.

Dr. Holmes testified that Ashley's current condition is what he would expect. When choosing between Drs. Holmes and Kinsbourne in holding what Ashley's TS sequelae would be, the court really cannot rely on Dr. Kinsbourne who has had no clinical experience in ten years and does not treat TS or any patients. Dr. Holmes both teaches at a well-established medical school and has a subspecialty in epilepsy. He cares for patients, including TS patients. It would be unreasonable, arbitrary, and capricious for the undersigned not to give greater weight to a man as accomplished as Dr. Holmes is in this field.

Under Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999), petitioner needs to prove that DPT was a substantial factor in causing Ashley's current condition or in significantly aggravating her TS to cause her current condition. At most, DPT was an insignificant (insubstantial) factor since although it triggered her initial seizure, those seizures for five years did not harm her and are quite different than her post-five-year-old seizures. If petitioner had proved "but for" the DPT, Ashley would never have seized and her condition would have been normal, that would be legally insufficient. According to the Federal Circuit, in Shyface, 165 F.3d at 1352, to prevail on the issue of entitlement, petitioner must prove that DPT was a substantial factor. The court, however, does not believe that "but for" the DPT vaccination, Ashley would never have seized. That she experienced a different, i.e., afebrile, seizure disorder after the age of five years shows she would have seized.

Respondent has proved that TS is a substantial factor in Ashley's current condition. In fact, respondent proved TS is the predominant factor in her current condition. Ashley fits well within the expected symptomatology of a child with severe TS: autism, afebrile seizures,

developmental delay, behavioral problems, and mental retardation. Dr. Kinsbourne's testimony that TS played a role in Ashley's current condition which he cannot separate from the DPT lends support to respondent's proof that TS is a substantial factor in her current condition. (He does not lend support to respondent's proof, of course, by positing that DPT is equally a substantial factor.)

Where the preexisting illness (here TS) is a substantial and predominant factor in causing the child's current condition, and the vaccine is an insubstantial factor (even if it reached the level of a "but for" factor), according to the Federal Circuit in Shyface, petitioner does not prevail. Even though Shyface was not a significant aggravation case, the analysis of causation in fact remains the same. To clear up any confusion, the court is not holding that petitioner ever had to prove DPT caused Ashley's first seizure since that is statutorily presumed. But she must prove that this vaccine injury is causally related to the child's current condition in order to satisfy her burden of proving significant aggravation. With respondent's evidence that TS is the substantial factor causing Ashley's current condition, petitioner has not satisfied her burden of showing a causal nexus between the vaccine injury and the current condition. Respondent has satisfied her burden of showing that a known factor unrelated caused Ashley's current condition.

In Whitecotton v. Secretary, HHS, 81 F.3d 1099 (Fed. Cir. 1996), the Federal Circuit assumed that once petitioners proved an on-Table injury and that the vaccinee's current condition was substantially worse than her prevaccination condition, petitioners proved a prima facie case of on-Table significant aggravation. The Federal Circuit assumed (and no evidence was in Whitecotton to rebut it) that the vaccine injury was causally related to the child's current condition. In this case, as in Jordan, supra, that is not a correct assumption. In addition, in Whitecotton, no one knew what was the factor unrelated to the vaccine that caused the vaccinee's

congenital microcephaly and so respondent could not rebut the presumed cause of the seizures and the current condition.

The TS cases are in a very different evidentiary posture. See Hanlon v. Secretary, HHS, No. 98-5120, 191 Fed. 3d 1344 (Fed. Cir. Sept. 8, 1999), cert. denied, 2000 WL 49173 (May 30, 2000); Plavin v. Secretary, HHS, No. 99-5168, 184 F.3d 1380 (Fed. Cir. Sept. 8, 1999) (affirming prior dismissals of TS cases in which the vaccinees do not have neurological reactions to DPT).

Petitioner herein has failed to impeach respondent's evidence that TS is the substantial, known factor unrelated causing Ashley's current condition. Therefore, the court finds that petitioner has failed to prove that DPT significantly aggravated Ashley's TS, since her presumed vaccine injury (the onset of seizures) did not cause her current condition.

CONCLUSION

This petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

DATED: _____

Laura D. Millman
Special Master